IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT PLC, MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED MALLINCKRODT HOSPITAL PRODUCTS IP UNLIMITED COMPANY, and INO THERAPEUTICS LLC,

Plaintiffs,

v.

AIRGAS THERAPEUTICS LLC and AIRGAS USA LLC,

Defendants.

Civil Action No. 22-1648-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Before me are Plaintiffs' motions for summary judgment and *Daubert* motions, and Defendants' motions for the same. (D.I. 375, 376, 377, 380, 381, 382, 383, 384, 385, 386, 387). I have reviewed the parties' briefing. (D.I. 378, 388, 395, 397, 401, 403, 435, 436). Before me is also Plaintiffs' motion to strike two of Defendants' non-infringement theories. (D.I. 394). I have reviewed that briefing, too. (*Id.*, 404, 406).

I. BACKGROUND

Plaintiffs Mallinckrodt plc, Mallinckrodt Pharmaceuticals Ireland Limited, Mallinckrodt Hospital Products IP Unlimited Company, and INO Therapeutics LLC (together, "Mallinckrodt") sued Defendants Airgas USA LLC and Airgas Therapeutics LLC (together, "Airgas"), alleging patent infringement. (D.I. 173 ¶ 1). Mallinckrodt alleges Airgas infringes five of its patents: U.S. Patent Nos. 8,776,794 (the "'6794 patent"), 8,776,795 (the "'795 patent"), 9,279,794 (the "'9794 patent"), 9,919,118 (the "'118 patent"), and 10,773,046 (the "'046 patent"). (*Id.*).

Mallinckrodt's patents cover its "INOmax" and "DS_{IR} Plus" products, which operate in the inhaled nitric oxide gas ("iNO") market. (*Id.* ¶¶ 33–35). iNO medication is typically administered bedside in a hospital, and most commonly to neonates and children suffering from hypoxic respiratory failure. (*Id.* ¶ 33). Mallinckrodt's INOmax product is nitric oxide 800 ppm and its DS_{IR} Plus product is a delivery system. (*Id.*). The asserted patents are generally directed to methods of treating patients using iNO while reducing the risk of adverse effects. (*Id.* ¶ 35). One claimed treatment is for neonates who suffer from left ventricular dysfunction ("LVD"). (*Id.*). If these patients take iNO, they have a high risk of experiencing serious adverse effects, like pulmonary edema. (*Id.*). Mallinckrodt affixes labels to its INOmax products with

instructions on how to safely administer INOmax to these high-risk patients. (*Id.* ¶ 36). Its patents reflect those methods and the delivery device. (*Id.*). Four of the patents are listed in the FDA's Orange Book for INOmax: the '741 patent, the '6794 patent, the '795 patent, and the '9794 patent. (*Id.* ¶ 1).

Airgas submitted ANDA No. 203144 seeking FDA approval of generic INOmax and a delivery system, called "Ulspira" and "Ulspira TS," respectively. (*Id.*). Mallinckrodt received notice of the ANDA and Airgas' challenge to its patents on November 18, 2022. (*Id.* ¶ 18). Mallinckrodt filed its Complaint on December 30, 2022. (D.I. 1). Mallinckrodt filed a motion for a preliminary injunction (D.I. 75), which I denied (D.I. 347). Airgas received approval for its ANDA on July 27, 2023. (D.I. 173 ¶ 76). Mallinckrodt filed a First Amended Complaint ("FAC"), pursuant to a stipulation between the parties, on February 12, 2024. (D.I. 172, 173).

Mallinckrodt currently asserts twenty claims from the five asserted patents. (D.I. 454-1 at 2 of 4).

II. LEGAL STANDARD

A. Summary Judgment

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). Material facts are those "that could affect the outcome" of the proceeding. *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). "[A] dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Id.* The burden on the moving party may be discharged by pointing out to the district court that there is

an absence of evidence supporting the non-moving party's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986); *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460–61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute . . . ." FED. R. CIV. P. 56(c)(1). The non-moving party's evidence "must amount to more than a scintilla, but may amount to less (in the evaluation of the court) than a preponderance." *Williams*, 891 F.2d at 461.

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

B. Expert Testimony

Federal Rule of Evidence 702 sets out the requirements for expert witness testimony and states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand

> the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

FED. R. EVID. 702. The Third Circuit has explained:

> Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit. Qualification refers to the requirement that the witness possess specialized expertise. We have interpreted this requirement liberally, holding that "a broad range of knowledge, skills, and training qualify an expert." Secondly, the testimony must be reliable; it "must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his o[r] her belief. In sum, *Daubert* holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity." Finally, Rule 702 requires that the expert testimony must fit the issues in the case. In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact. The Supreme Court explained in *Daubert* that "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility."
>
> By means of a so-called "*Daubert* hearing," the district court acts as a gatekeeper, preventing opinion testimony that does not meet the requirements of qualification, reliability and fit from reaching the jury. *See Daubert* ("Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a) [of the Federal Rules of Evidence] whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.").

Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404–05 (3d Cir. 2003) (footnote and internal citations omitted).

C. Motion to Strike

Experts must provide "a complete statement of all opinions [they] will express and the basis and reasons for them." FED. R. CIV. P. 26(a)(2)(B)(i). "If a party fails to provide information . . . as required by Rule 26(a) . . . , the party is not allowed to use that information . . . to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." FED. R. CIV. P. 37(c)(1).

Courts in the Third Circuit consider the *Pennypack* factors when deciding whether a violation of Rule 26(a) warrants striking the expert's testimony:

> (1) "[T]he prejudice or surprise in fact of the party against whom the excluded witnesses would have testified" or the excluded evidence would have been offered; (2) "the ability of that party to cure the prejudice"; (3) the extent to which allowing such witnesses or evidence would "disrupt the orderly and efficient trial of the case or of other cases in the court"; (4) any "bad faith or willfulness in failing to comply with the court's order"; and (5) the importance of the excluded evidence.

ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254, 298 (3d Cir. 2012) (quoting *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904–05 (3d Cir. 1977)).

III. DISCUSSION

A. Summary Judgment Motions

1. Hypothetical Negotiation Date

Mallinckrodt moves for a summary judgment ruling that the hypothetical negotiation date for a reasonable royalty is November 2022, the date Airgas amended its ANDA to include paragraph IV certifications for the patents listed in the Orange Book for INOmax. (D.I. 388 at 5). Airgas argues the proper date is November 2023, the date Airgas launched Ulspira. (D.I. 397 at 2).

The hypothetical negotiation date for a reasonable royalty is "the date infringement began, even if damages cannot be collected until some time later." *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 75 (Fed. Cir. 2012) (citing *Wang Lab'ys v. Toshiba Corp.*, 993 F.2d 868, 870 (Fed. Cir. 1993)). Under the Hatch-Waxman Act, filing an ANDA is an "artificial" act of infringement that allows the NDA holder to file a patent infringement suit. *See Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 136 F.4th 1075, 1086 (Fed. Cir. 2025) (citing *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997)). Mallinckrodt argues this "artificial" infringement date should be the hypothetical negotiation date. I disagree.

While true that Airgas filing an ANDA and paragraph IV certifications is an act of infringement at least for purposes of giving Mallinckrodt the ability to sue Airgas, *A/S/ v. Lupin Ltd.*, 87 F.4th 1361, 1365 (Fed. Cir. 2023), I think the hypothetical negotiation scenario is different. The hypothetical negotiation is a "willing licensor-willing licensee approach," which "attempts to ascertain the royalty upon which the parties would have agreed had they successfully negotiated an agreement just before infringement began." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1325 (Fed. Cir. 2009) (internal quotations and citations omitted). The hypothetical negotiation contemplating a "willing licensor-willing licensee" negotiation on the eve of infringement indicates the negotiation is based on a scenario where an infringer needs a license for its imminent launch. An ANDA holder does not need a license to file its ANDA, even if that ANDA is found to infringe. But the ANDA holder would need a license to launch the infringing product. The "willing licensor-willing licensee" framework makes little sense if the hypothetical negotiation date is a date when a license is not needed.[1] The appropriate hypothetical negotiation date is thus November 2023, when Airgas launched its product.

Mallinckrodt's motion (D.I. 380) is denied.

2. Anticipation

Mallinckrodt seeks summary judgment that claims 24, 26, 29, and 33 of the '741 patent are not anticipated.[2] (D.I. 388 at 7). In light of Mallinckrodt's narrowing of claims to eliminate the '741 patent from this case, I dismiss the summary judgment motion as moot.

[1] I note that the date of the hypothetical negotiation is a separate inquiry from the date(s) used to calculate damages. *See Wang*, 993 F.3d at 870. Thus, while it is true that Mallinckrodt did not suffer any damages in November 2022, that is not the reason it is the wrong date. It is the wrong date because Airgas did not need a license then.

[2] When discussing a group of claims in a given section of this opinion, I will refer to those claims as "the claims."

3. Obviousness

Mallinckrodt seeks summary judgment that claims 24, 26, 29, 30, and 33 of the '741 patent, claims 7, 8, and 13 of the '6794 patent, claims 1, 7, 8, and 13 of the '795 patent, claim 6 of the '9794 patent, and claims 1 and 12 of the '118 patent are not invalid as obvious. (D.I. 388 at 9). Mallinckrodt argues that Airgas' expert failed to show there was a motivation to combine prior art references. (*Id.*). Since the '741 patent has been removed from the case (D.I. 440), and since claim 1 of the '795 patent and claims 1 and 12 of the '118 patent have also been removed (D.I. 454-1 at 2 of 4), the motion as to the '741 patent and to the above-mentioned claims is dismissed as moot.

A patent may be invalid as obvious "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. For multiple prior art references to render a patent obvious, a person having ordinary skill in the art ("POSA") must have been motivated to combine the references. *See Par Pharm., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014). "The presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact." *Id.* (quoting *Alza Corp. v. Mylan Lab'ys, Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006)).

a. Claims 7, 8, and 13 of the '6794 patent, and claims 7, 8, and 13 of the '795 patent

Airgas' expert, Mr. Donald Beduhn, opines that claims 7, 8, and 13 of the '6794 patent and claims 7, 8, and 13 of the '795 patent are rendered obvious by two of Mallinckrodt's earlier-released (and therefore prior art) iNO delivery devices. (D.I. 389-1 at 247–319 of 357).

Independent claim 7 of the '6794 patent and independent claim 7 of the '795 patent contain the same relevant limitation.[3] Claim 7 of the '795 patent recites:

> 7. A therapy gas delivery system comprising:
> a gas delivery device comprising:
> a gas source;
> a valve attached to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve; and
> a circuit comprising:
> *a first memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration of the gas source*; and
> a first processor and a first transceiver in communication with the first memory; and
> a control module that controls delivery of therapy gas to a subject, the control module comprising a second memory, a second transceiver and a second processor, wherein the second transceiver and the second processor are in communication with the second memory,
> wherein the first transceiver and the second transceiver send and receive signals to communicate the gas data to the control module and to verify one or more of the gas identification, the gas concentration and that the gas is not expired.

('795 patent at 17:6–26) (emphasis added).

Mallinckrodt argues Mr. Beduhn fails to show the prior iNO devices disclose "a first memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration" of the independent claims.

Mr. Beduhn opines that the element was disclosed by Mallinckrodt's earlier iNO delivery device having a configuration screen during the boot-up process, where a user can "select[] the ppm value of the gas cylinder that is attached to the machine." (D.I. 389-1 at 257 of 357). Mr. Beduhn understands this means "the configuration screen stores the NO cylinder concentration." (*Id.* at 260 of 357). In Mr. Beduhn's opinion, "this storage of the cylinder concentration value is

[3] Claims 8 and 13 of the '6794 patent, and claims 8 and 13 of the '795 patent depend from the independent claims containing the limitation at issue.

the claimed memory to store gas data comprising one or more of gas identification, gas expiration and gas concentration." (*Id.*).

I issued a claim construction order, construing "gas data" as "data of the actual gas inside the gas source." (D.I. 287 at 1). Mallinckrodt argues, "The data entered by the [user] during boot-up is simply an arbitrary value entered via the interface and not 'data of the actual gas inside the gas source.'" (D.I. 388 at 13).

Airgas argues that there is a dispute of material fact on whether the user-implemented gas concentration of Mallinckrodt's earlier iNO delivery device is the "data of the actual gas inside the gas source," citing Mr. Beduhn's deposition testimony. (D.I. 397 at 9). Mr. Beduhn testified that the gas concentration number on the device could be changed to be different from the actual gas inside the gas source, but that he "can't conceive" that field engineers using the device would fail to ensure that the numbers match. (D.I. 389-1 at 340 of 357).

I think there is a genuine dispute of material fact that renders summary judgment inappropriate. Mallinckrodt seems to desire the claims to require automatically displaying data of the actual gas inside the gas source. But the claims and the claim construction are not so limiting. I think they leave open the possibility of the "gas data" being manually inputted (that is, by a human), so long as that "gas data" is "data of the actual gas inside the gas source." Mr. Beduhn's opinion, that "gas data" is shown in Mallinckrodt's previous delivery device with a user selecting the ppm value of the gas cylinder, could meet the limitation. Mallinckrodt's motion (D.I. 382) that claims 7, 8, and 13 of the '6794 patent, and claims 7, 8, and 13 of the '795 patent are obvious is denied.

b. Claim 6 of the '9794 patent, and claims 1 and 12 of the '118 patent

Claim 6 of the '9794 patent and claims 1 and 12 of the '118 patent require a "slope" and "calibration." (*See* D.I. 388 at 14–15). Claims 1 and 12 are no longer asserted but claims that depend upon them are still asserted. (D.I. 454-1 at 2 of 4). So, for ease of understanding, I set forth claim 1 of the '118 patent, which recites:

> 1. A method for delivering notifications of a calibration status for a sensor associated with a therapeutic gas delivery device, the method comprising:
>
> *storing in memory a baseline calibration value, slope, and calibration schedule*;
>
> monitoring a patient intake of therapeutic gas with a sensor;
>
> delivering, via a therapeutic gas delivery device, a predetermined dosage of therapeutic gas to the patient;
>
> measuring a concentration of therapeutic gas from the delivered predetermined dosage;
>
> retrieving, from memory, the baseline calibration value, slope and calibration schedule;
>
> performing a calibration according to the calibration schedule, wherein the calibration includes exposing the sensor to a zero concentration of the therapeutic gas and adjusting the baseline calibration value according to a sensor output value during the calibration;
>
> notifying a user, during the performance of the calibration, that the calibration is currently in effect, wherein the notifying includes displaying a notification that the measuring of therapeutic gas concentration is off-line; and
>
> *upon completion of the calibration, determining an actual concentration of therapeutic gas delivered in the predetermined dosage to compensate for sensor drift by adjusting the value of the measured concentration based on the adjusted baseline value and the slope.*

('118 patent at 31:59–32:20) (emphasis added).

Mr. Beduhn acknowledges that Mallinckrodt's prior art iNO delivery devices do not contain the "determining an actual concentration" element. He opines, however, that it would have been obvious to modify those devices to include the missing element. (D.I. 389-1 at 169–70 of 357).

Mallinckrodt argues that the claims require calibration with no "recalculation" of the slope, while its prior art devices do require the slope to be recalculated for each calibration. (D.I. 388 at 14–15). Mr. Beduhn opines that the prior art devices did not need to recalculate the slope

for each calibration simply because a slope "changes or drifts on the order of a month, . . . not over the course of a single day." (D.I. 389-1 at 192 of 357). Mr. Beduhn opines that a POSA would have been motivated to modify the prior art devices to not recalculate the slope during calibration. (*Id.* at 192–95 of 357). Mallinckrodt argues that the only way to do this would be to change the source code, which was confidential and not available to the public, and thus not known to a POSA. (D.I. 388 at 15–16). Mallinckrodt argues that since the problem was not known, there was no motivation to modify its earlier devices. (*Id.* at 16).

Airgas argues that Mallinckrodt mischaracterizes Mr. Beduhn's opinion. (D.I. 397 at 10). Mr. Beduhn opines that "there is no definitive evidence of the actual slope recalculation (if any) that was performed by" Mallinckrodt's prior art devices. (D.I. 389-1 at 192 of 357). That is because the source code for those prior art devices was not produced. (*Id.*). Mr. Beduhn explains that, since there is no definitive evidence, "the only thing left is to infer what a reasonable function would be." (D.I. 389-2 at 4 of 360). Mr. Beduhn offers two opinions. The first is that "it is reasonable to assume a slope recalculation was not performed by the" prior art device. (*Id.*). The second is that, assuming the prior art device does recalculate the slope, it would have been obvious to modify the device. Mallinckrodt only challenges the second opinion.

The dispute comes down to whether the problem with Mallinckrodt's prior art devices (recalculating the slope for each calibration) was known to a POSA. Mr. Beduhn does not seem to address this in his reports. Airgas argues that a POSA could figure out the problem by reading the devices' manuals; Airgas does not cite to Mr. Beduhn's report for this argument. (D.I. 397 at 12). Airgas argues that hidden features of a device are considered part of the prior art. (*Id.* at 11–12). But what is part of the prior art is a separate inquiry from whether a POSA knew of a

problem and thus was motivated to solve that problem. Airgas argues that Mallinckrodt "conceded other aspects of their own prior art machines were amenable to modification or part of the public prior art, even though their function was only understood with respect to source code." (D.I. 397 at 13). Even if true, Airgas does not explain why this means that summary judgment must be denied.

If "ordinary artisans would not have thought to try [the claimed invention] at all because they would not have recognized the problem," then the claims are not obvious. *Leo Pharm. Prods. v. Rea*, 726 F.3d 1346, 1357 (Fed. Cir. 2013). Mallinckrodt cites to Mr. Beduhn's deposition testimony, where he testified that the source code was not publicly available and that if a POSA did not know of the problem, there would be no motivation to fix the problem. (D.I. 388 at 16). I think there is no dispute of material fact here. The parties agree that the source code was not publicly available, and Airgas points to nothing in Mr. Beduhn's report that shows a POSA would have known of the problem in Mallinckrodt's previous device. Indeed, Mr. Beduhn admitted, "If [POSA] didn't know there was a problem, I don't think there's any evidence there is a problem to fix." (D.I. 389-1 at 348 of 357). Airgas bears the burden to show obviousness. I think Airgas failed to show any evidence that a POSA knew of the purported problem and would have been motivated to fix the problem.

Mallinckrodt has shown it is entitled to summary judgment that claim 6 of the '9794 patent and claims 1 and 12 of the '118 patent are not obvious. Since they are not obvious, claims that depend from them would also be not obvious. That part of Mallinckrodt's motion (D.I. 382) is granted.

4. Patentability

Airgas moves for summary judgment that claims 24, 26, 29, 30, and 33 of the '741 patent are invalid under 35 U.S.C. § 101. (D.I. 378 at 2). Mallinckrodt moves for summary judgment that claim 26 of the '741 patent is not invalid under 35 U.S.C. § 101. (D.I. 388 at 17). Since the '741 patent is no longer asserted, both motions are dismissed as moot.

5. Infringement

Airgas moves for summary judgment of noninfringement on two grounds.

a. The '795 patent and the '6794 patent claims

Airgas moves for a summary judgment ruling that it does not infringe claims 1 and 7 of the '795 patent and claim 1 of the '6794 patent. (D.I. 378 at 7). Mallinckrodt no longer asserts claim 1 of the '795 patent and claim 1 of the '6794 patent. (D.I. 454-1 at 2 of 4). That part of the motion is dismissed as moot.

Claim 7 of the '795 recites,

> 7. A therapy gas delivery system comprising:
> a gas delivery device comprising:
> a gas source;
> a valve attached to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve; and
> a circuit comprising:
> a first memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration of the gas source; and
> a first processor and a first transceiver in communication with the first memory; and
> a control module that controls delivery of therapy gas to a subject, the control module comprising a second memory, a second transceiver and a second processor, wherein the second transceiver and the second processor are in communication with the second memory,
> wherein the first transceiver and the second transceiver send and receive signals to communicate the gas data to the control module and *to verify one or more of the gas identification, the gas concentration and that the gas is not expired.*

('795 patent at 17:6–26) (emphasis added). Airgas argues its Ulspira TS device does not perform the claimed element of "verify[ing] . . . the gas concentration" required by the claim.

Mallinckrodt alleges that Ulspira TS infringes the limitation with its "pre-use check procedure." (D.I. 378 at 9). Airgas characterizes this procedure as "Ulspira TS test[ing] its nitric oxide dosing at a certain level and verif[ying] that the output is within an acceptable and expected range (i.e. the tolerance)," the accepted range being a 30% tolerance. (*Id.*). Airgas argues that Ulspira TS does not meet the limitation for two reasons: (1) "failing the performance test merely indicates that 'something is incorrect'" and (2) "passing the performance test . . . does not verify anything about the gas cylinder concentration" because of the 30% tolerance. (D.I. 378 at 22). By way of example, Airgas explains that if Ulspira TS is configured to receive a 900 ppm cylinder, but was connected to an 800 ppm cylinder, the gas concentration would be off by 11%, but the performance test would "verify" the concentration due to the 30% tolerance. (*Id.* at 24). Airgas argues this cannot satisfy the "verify" limitation of claim 7. (*Id.*).

Mallinckrodt's experts opine that the pre-use check procedure meets the limitation of "verify . . . the gas concentration." (*See* D.I. 396-1 at 87 of 196 (Goodin); *id.* at 127 of 196 (DiBlasi)). One of Mallinckrodt's experts opines that Ulspira TS will "verify that the right NO gas and concentration is hooked up to the machine before delivery is started to the patient." (*Id.* at 127 of 196). "[I]f the wrong gas or concentration is hooked up to the machine, this test will fail." (*Id.*).

Though Airgas may be right that Ulspira TS can produce a false positive, that does not preclude the possibility that Ulspira TS can produce a true positive (that is, correctly "verify . . . the gas concentration"). There is no requirement in patent law that the accused product must always infringe. *See ParkerVision, Inc. v. Qualcomm Inc.*, 903 F.3d 1354, 1361 (Fed. Cir. 2018). There is a dispute of material fact at least as to whether Ulspira TS infringes.

Airgas argues that the pre-use check procedure is used primarily to verify the device is working and the dosage is correct. (D.I. 403 at 9). That may be true. But if a device sometimes infringes and sometimes does not infringe, it is still an infringing device. Mallinckrodt's experts are of the opinion that this step also requires verification of the gas concentration. (*See* D.I. 396-1 at 87 of 196; *id.* at 127 of 196). That is supported by Airgas' Ulspira TS System Design Description saying, "The Dosage test administers NO to the test circuit and verifies that the measured NO concentration is within tolerance." (D.I. 378-5 at 78 of 93).

Airgas also argues that the only cylinders available in the United States are 800 ppm, so "there is nothing to verify." (D.I. 378 at 26). Even if that is true, Ulspira TS is still capable of "verifying" the concentration; that is, verifying that it is connected to a 800 ppm cylinder.

Airgas' motion for summary judgment of non-infringement of claim 7 of the '795 patent (D.I. 376) is denied.

b. The '046 patent claims

Airgas moves for a summary judgment ruling that it does not infringe claim 1 of the '046 patent.[4] If Airgas is right, then none of the asserted claims of the '046 patent would be infringed.

Claim 1 of the '046 patent recites,

> 1. An apparatus to deliver therapeutic gas to a patient, the apparatus comprising:
> a therapeutic gas supply comprising nitric oxide;
> a therapeutic gas injector module comprising a first inlet in fluid communication with the therapeutic gas supply, a second inlet in fluid communication with a breathing gas delivery system that provides a breathing gas, and an outlet in fluid communication with the first inlet and the second inlet to supply a mixture of the breathing gas and the therapeutic gas to the patient, the therapeutic gas injector module in communication with the therapeutic gas supply to control the flow of therapeutic gas to the patient and achieve a desired dose of therapeutic gas administered to the patient;

[4] Airgas no longer asserts claim 1, but all the other asserted claims of the '046 patent (claims 3, 6, 11, and 17) depend from claim 1. ('046 patent at 12:33–14:23).

> a flow sensor operable to measure the flow of the breathing gas;
> a display in communication with the therapeutic gas injector module; and
> a control circuit in communication with the therapeutic gas injector module and the display, the control circuit operable to *calculate a delivery concentration of the therapeutic gas and operable to send data to the display to produce an indicator to inform the user of the apparatus when the calculated delivery concentration is in one of a target delivery region, an under-delivery of nitric oxide region, and an over-delivery of nitric oxide region.*

('046 patent at 12:6–32) (emphasis added). Mallinckrodt alleges Ulspira TS' pre-use check performance test infringes the claim. Airgas argues its Ulspira TS device does not meet two limitations of claim 1.

First, Airgas argues Ulspira TS' pre-use check performance test does not deliver NO gas to a patient and it therefore does not, among other things, "calculate a delivery concentration." (D.I. 378 at 26, 29). Mallinckrodt argues claim 1 does not require the calculated delivery concentration to be delivered to a patient. (D.I. 395 at 21).

Airgas' argument is based on the idea that the '046 patent claims require delivery to a patient. Airgas cites Mallinckrodt's expert report for support. Airgas quotes Mallinckrodt's expert as opining, "[T]he entire point of using the Ulspira device on patients" is "that at the appropriate dosage, the delivered NO therapy gas—which is controlled by the user-set desired dosage setting in the [graphical user interface] module—can be effective to treat or prevent hypoxic respiratory failure." (D.I. 378 at 29). But this quote says nothing about what is required by the claims. Indeed, the claims require "the control circuit *operable* to calculate a delivery concentration of the therapeutic gas." ('046 patent at 12:6–32) (emphasis added). The claims do not require that the measured gas concentration be delivered to a patient. Airgas does not argue otherwise; Airgas instead points to Mallinckrodt's expert reports, but those reports also do not explicitly say that "delivery" must be to a patient. (*See* D.I. 403 at 14). Airgas argues that those expert reports must be referring to delivery to a patient based on the mechanisms of iNO delivery

(D.I. 403 at 14–15), but again, this has nothing to do with what the claims require. Airgas has not met its burden to show that there are no disputes of material fact and that as a matter of law it does not infringe this element.

Second, Airgas argues Ulspira TS "does not achieve the alleged 'invention' of the ['046 patent] of diagnosing alarms that occur during the delivery of nitric oxide gas to a patient." (D.I. 378 at 30). Airgas cites to two of Mallinckrodt's experts, who are said to identify the '046 patent's "invention" as solving a problem called "sensor drift." (*Id.* at 30–31). Infringement is proven by comparing claim language to an accused product. *See Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1273 (Fed. Cir. 2004). The claims do not contain the words "sensor drift." The portions of Mallinckrodt's experts' declarations cited by Airgas do not rely upon an understanding that the claims have some limitation relating to "sensor drift." (*See* D.I. 378-13 at 9 of 13; D.I. 378-15 at 10 of 11). Airgas has not pointed to a specific claim limitation that it alleges its Ulspira TS product does not practice (other than the "delivery" limitation, which I have already rejected above). Airgas has not shown it is entitled to judgment as a matter of law that it does not infringe the '046 patent claims. Airgas' motion (D.I. 376) is denied.

c. Indirect Infringement

Airgas moves for summary judgment of no indirect infringement on the basis that Mallinckrodt cannot prove direct infringement of the '6794 patent, the '759 patent, and the '046 patent claims, based on Airgas' foregoing arguments. (D.I. 378 at 31). Since I deny Airgas' motion with respect to direct infringement, I also deny it with respect to indirect infringement.

B. *Daubert* Motions

There are six Daubert motions. I will first address the one that relates to infringement testimony. I will then address the other five, which relate to damages.

1. Andrew Atz

Mallinckrodt moves to exclude testimony of Dr. Atz, a technical expert. Dr. Atz opines that Airgas does not induce infringement of the '741 patent. (D.I. 387). The motion is moot. (D.I. 440). It is dismissed as moot.

2. Ivan Hofmann

Mallinckrodt moves to exclude three parts of testimony from Airgas' damages expert, Ivan Hofmann: his opinions on the hypothetical negotiation, non-infringing alternatives, and design-arounds. (D.I. 388 at 29, 31).

a. Hypothetical Negotiation

Mallinckrodt has two related issues with Mr. Hofmann's hypothetical negotiation testimony: the hypothetical negotiation date and potential hindsight bias. Both are based on Mallinckrodt's argument that the hypothetical negotiation date should be November 2022. (*Id.* at 29–31). As I explain above, the hypothetical negotiation date is November 2023. This part of Mallinckrodt's motion (D.I. 385) denied.

b. Non-Infringing Alternatives

Mallinckrodt takes issue with Mr. Hofmann's opinions about non-infringing alternatives.

Mr. Hofmann opines that the availability of non-infringing alternatives would have affected the parties' negotiations. Mr. Hofmann opines that Praxair iNO and delivery products (available at the time of the hypothetical negotiation) were non-infringing alternatives, because Praxair's products were found not to infringe various claims of the '6794 patent, the '795 patent, and the '9794 patent. (D.I. 388 at 32). Mallinckrodt takes issue with this testimony because there are patent claims asserted in this case that were not asserted in the Praxair litigation, including all the asserted claims of two patents that were not at issue in that case. (*Id.*). I am not

sure that Mr. Hofmann is actually giving an opinion that past litigation means the relevant products would be non-infringing alternatives if made by Airgas. Mallinckrodt cites to his expert report (*id.*), but his expert report does not actually seem to offer that opinion (D.I. 389-1 at 65 of 357 n.110; *id.* at 67 of 357 n.177). He seems simply to be reciting what counsel told him. I doubt that Mr. Hofmann, whose expertise is some combination of economics and damages, is qualified to offer expert opinions about the interpretation of ANDA litigation. To the extent Mr. Hofmann would testify that the prior litigation determined anything about the non-infringing status of any claims other than the ones that were at issue, I would exclude that. Since, as I explain below, he has other bases for his non-infringing alternatives opinion, I do not grant Mallinckrodt's motion to exclude all of Mr. Hofmann's non-infringing alternatives testimony.

Mallinckrodt takes issue with Mr. Hofmann's deposition testimony opining that Mallinckrodt's decision not to sue some companies for patent infringement indicates there may be non-infringing alternatives. (D.I. 388 at 32). In his deposition testimony, Mr. Hofmann says, for example, "I'm pointing out that these products are, in fact, commercialized and being sold by a competitor [*i.e.*, Praxair] that has been sued before by Mallinckrodt, and the absence of further pursuit of litigation, you know, gives an indication that they are non-infringing alternatives." (D.I. 389-1 at 101 of 357). Mallinckrodt cites to two cases for support, both of which are distinguishable. Both cases excluded expert testimony of non-infringing alternatives when the entire bases of the experts' opinions was that the potential non-infringing alternatives were not accused of infringing. *See IPA Techs. Inc. v. Microsoft Corp.*, 2024 WL 1797394, at *9 (D. Del. Apr. 25, 2024); *Acceleration Bay LLC v. Activision Blizzard Inc.*, 2019 WL 4194060, at *8 (D. Del. Sept. 4, 2019). That is not the sole basis for Mr. Hofmann's non-infringing alternatives opinion. He also bases his opinion on an FDA approval letter to Praxair, Praxair's submissions

to the FDA, and Mr. Donald Beduhn's technical opinion. (D.I. 389-1 at 64–67, 74 of 357). As Mallinckrodt acknowledges, Mr. Hofmann recognizes that the failure to pursue infringement claims against Praxair is not dispositive of non-infringement. (D.I. 388 at 32).

Mallinckrodt's motion (D.I. 385) with respect to Mr. Hofmann's non-infringing alternatives opinion is denied.

c. Design-Around

Mallinckrodt takes issue with Mr. Hofmann's "design-around" analysis. (*Id.* at 33). Mr. Hofmann considers factors in determining the cost and availability of a design-around at the time of the hypothetical negotiation. (*See* D.I. 389-1 at 68 of 357). However, according to Mallinckrodt, Mr. Hofmann failed to adequately analyze the factors. (D.I. 388 at 34). Mallinckrodt has three specific problems with the analysis.

First, Mallinckrodt argues Mr. Hofmann uses the wrong standard for "availability." (D.I. 388 at 34). I take it that Mallinckrodt thinks the "right" standard is considering "the costs the infringer would incur to produce a non-infringing product," "technical and practical obstacles to marketing a non-infringing [product]," and "the FDA regulatory delay." (*Id.* at 33 (quoting *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1334–35 (Fed. Cir. 2015) ("*AstraZeneca II*")). Mallinckrodt argues Mr. Hofmann's "availability" opinion is based solely on "the mere presence of other available products that haven't been sued." (D.I. 388 at 34). This argument is substantially the same argument Mallinckrodt offers with respect to the Mr. Beduhn's opinion on the availability of non-infringing alternatives. (*See id.* at 32–33). Mr. Hofmann bases his opinion on the availability of design-arounds on the same facts on which he bases his opinion on the availability of non-infringing alternatives, including relying on Mr. Beduhn for the opinion "that various design-around options are, and have been, available to Airgas." (D.I. 389-1 at 69

of 357). I do not think Mallinckrodt's argument is any more successful here than it is in regard to non-infringing alternatives.

Second, Mallinckrodt takes issue with the fact that Mr. Hofmann did not determine the costs of a design-around. (D.I. 388 at 34). Airgas does not directly address this in its brief. "A price for a hypothetical license may appropriately be based on consideration of the 'costs and availability of non-infringing alternatives' and the potential infringer's 'cost savings.'" *Prism Techs. LLC v. Sprint Spectrum L.P.*, 849 F.3d 1360, 1376 (Fed. Cir. 2017) (quoting *Aqua Shield v. Inter Pool Cover Team*, 774 F.3d 766, 771–72 (Fed. Cir. 2014)). Mr. Hofmann opines it cost Airgas $5.8 million to develop Ulspira, and that that cost "provides an estimate of the maximum amount that it may cost to design-around the [patents]." (D.I. 389-1 at 74 of 357). But that is not the cost of a design-around. That is the cost of what Airgas actually did. Mr. Hofmann considers design-arounds, but he gives no analysis as to the price of any of them (at least nothing cited by the parties). I think that renders his opinions about design-around options, and how they would affect a hypothetical negotiation, methodologically unsound.

Third, Mallinckrodt argues that Mr. Hofmann failed to consider the effect a design-around would have on Airgas' "path to market." (D.I. 388 at 34). Mallinckrodt argues Mr. Hofmann improperly assumes a delay would have no effect on Airgas' FDA approval or impact in the market. (*Id.* at 34–35). I think that is a factual issue that could be explored on cross-examination.

Since I agree with the second of Mallinckrodt's three arguments, Mallinckrodt's motion (D.I. 385) with respect to Mr. Hofmann's design-around analysis is granted.

3. Dana Trexler

Airgas moves to exclude testimony of Mallinckrodt's damages expert, Ms. Trexler.

Ms. Trexler's report contains opinions for several different infringement scenarios. Airgas seeks to exclude Ms. Trexler's "Scenario 1," which "assumes that at least one asserted claim of the four Asserted Patents that are listed in the Orange Book . . . is found to be infringed by Airgas." (D.I. 378-19 at 5 of 54). Ms. Trexler recognizes that "if at least one of the Asserted Orange Book Patents is found to be infringed by Airgas, the FDA approval date is reset to the last expiration date of the infringed patent(s), which would delay Airgas[']s commercial launch, and corresponding profits, of Ulspira." (*Id.* at 5–6 of 54). The Orange Book patents have three different expiration dates. (*Id.* at 6 of 54). Ms. Trexler calculated three potential lump sums, depending on which patent(s) are found to be infringed, based on the length of delay. (*Id.*). Ms. Trexler's lump sums are ranges, from Airgas' "projected incremental at-risk profits" on the lower end to Mallinckrodt's "at-risk profits resulting from the potential loss of customer contracts or additional price erosion" at the higher end. (*See* D.I. 395 at 27).

Airgas has two issues with Ms. Trexler's method.

a. Apportionment

First, Airgas argues takes issue with the entire Scenario 1 method, arguing Ms. Trexler fails to apportion value to the infringing features of Airgas' product. (D.I. 378 at 33). Indeed, Ms. Trexler opines with respect to *Georgia-Pacific* factor thirteen (the portion of profit credited to the patented invention, distinguished from the non-patented elements),

> The hypothetical negotiation under Scenario 1 would have been conducted under the regulations of the Hatch-Waxman Act, which provides for redating of the approval upon a finding of infringement of any of the Orange Book patents. Because of this regulatory requirement, from an economic perspective, the value of any of the Asserted Orange Book Patents is tied to the profits on the entirety of the Covered and Accused Products. Therefore, it is my opinion that consideration of the entirety of Airgas' discounted incremental at-risk profits and Mallinckrodt's discounted at-risk profits in the determination of the reasonable royalty does not require further apportionment.

(D.I. 378-19 at 13 of 54). Ms. Trexler also does not "apportion profits between the gas, service, and device because FDA approval for [Ulspira] was dependent upon the approval of the device, and . . . vice versa." (*Id.* at 15 of 54). Airgas argues that Ms. Trexler impermissibly adopts an "entire market value theory rather than apportioning her reasonable royalty as required here where the patents cover only distinct parts of a multi-part product." (D.I. 378 at 36).

"[W]here multi-component products are involved, the governing rule is that the ultimate combination of royalty base and royalty rate must reflect the value attributable to the infringing features of the product, and no more." *Ericsson, Inc. v. D-Link Sys.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014) (citing *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1326 (Fed. Cir. 2014)). "The entire market value rule is a narrow exception to this general rule. If it can be shown that the patented feature drives the demand for an entire multi-component product, a patentee may be awarded damages as a percentage of revenues or profits attributable to the entire product." *LaserDynamics*, 694 F.3d at 67 (citing *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1549, 1551 (Fed. Cir. 1995)). "[T]he trial court must carefully tie proof of damages to the claimed invention's footprint in the market place." *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869 (Fed. Cir. 2010) (citing *Grain Processing Corp. v. American Maize-Prods, Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999)).

Airgas argues Ms. Trexler "has no support for her novel theory that an alleged potential change in FDA approval status justifies awarding sweeping damages based on entire market value." (D.I. 378 at 38).

Mallinckrodt argues that Ms. Trexler's reasonable royalty analysis properly considered the *Georgia-Pacific* factors and focused on the parties' expectations at the time of the hypothetical negotiation. (D.I. 395 at 25). Namely, Mallinckrodt argues that Airgas chose to

enter the iNO market through Hatch-Waxman litigation, thus "expos[ing] themselves to the risk that an adverse district court decision would result in FDA redating the approval date of its ANDA." (*Id.* at 26). Mallinckrodt argues that Airgas would have feared regulatory approval delays, which "is what the parties would have been negotiating for in Ms. Trexler's Scenario 1." (*Id.* at 27). Mallinckrodt cites to *Amgen Inc. v. Hospira Inc.*, 336 F. Supp. 3d 333 (D. Del. 2018), *aff'd*, 944 F.3d 1327 (Fed. Cir. 2019), for support that this approach is appropriate. (D.I. 395 at 29).

I do not think *Amgen* helps Mallinckrodt. Mallinckrodt argues *Amgen* is analogous because an expert for the plaintiff in that case focused on the value of a potential regulatory delay. (D.I. 395 at 30). While that may be true, that case focused not on a failure to apportion, but whether a jury could properly award damages based at least in part on an expert's testimony about a hypothetical negotiation with hypothetical facts that were contrary to what happened in real life. *Amgen*, 336 F. Supp. 3d at 350. That case held it was reasonable for the jury to award damages between the hypothetical negotiation number and the actual damages number. *Id.* at 351. There is no mention of apportionment, or any indication that the defendant in that case alleged that the plaintiff's damages expert failed to apportion.

Mallinckrodt argues that Ms. Trexler meets the apportionment requirement in three ways: by analyzing the *Georgia-Pacific* factors, by considering the incremental value the patented invention adds to the end product, and by analogy to the (lack of) apportionment found proper in *AstraZeneca II*. (D.I. 395 at 31–39). I evaluate each in turn.

i. *Georgia-Pacific* Factors

Airgas cites *Exmark* for the proposition, "[A]pportionment can be done . . . through a thorough and reliable analysis to apportion the royalty rate," including "through a proper analysis

of the *Georgia-Pacific* factors."[5] *Exmark Mfg. Co. v. Briggs & Stratton Power Prods. Grp., LLC*, 879 F.3d 1332, 1348–49 (Fed. Cir. 2018). "[T]he standard *Georgia-Pacific* reasonable royalty analysis takes account of the importance of the inventive contribution in determining the royalty rate that would have emerged from the hypothetical negotiation." *Id.* at 1349 (quoting *AstraZeneca II*, 782 F.3d at 1338). "The essential requirement is that the ultimate reasonable royalty award must be based on the incremental value that the patented invention adds to the end product." *Id.* at 1348.

I note that *Exmark* is different from this case. There, the claim was for a conventional multi-blade lawn mower with a novel flow control baffle. *Id.* at 1338. Because the accused product was a conventional multi-blade lawn mower with a flow control baffle, it had "no unpatented or non-infringing feature." *Id.* at 1348. The court cited *AstraZeneca II* for support that an analysis of the *Georgia-Pacific* factors could be sufficient to apportion between "conventional and unconventional elements." *Id.* (quoting *AstraZeneca II*, 782 F.3d at 1338). Below I explain, in addressing another of Mallinckrodt's arguments, that *AstraZeneca II* is distinguishable from this case because the products are accused of infringing two different inventions; none of the patents singly claims the two distinct inventions. Rather, each of them covers an improvement to existing devices or methods. The way Ms. Trexler summarizes the patents is that they are two "pre-use gas verification" patents and a "sensor calibration" patent. (D.I. 378-19 at 8 of 54). I assume that, at a high level, her summaries capture the unconventional elements of the inventions. Each invention is different. Each has an unconventional element and conventional elements. The accused products have the conventional and the unconventional

[5] Notwithstanding that apportionment could be done by "thorough and reliable analysis," the expert's analysis was insufficient. *Exmark*, 879 F.3d at 1349.

elements. No one patent covers all the unconventional elements. Regardless, I do not think Ms. Trexler has effectively apportioned in her *Georgia-Pacific* analysis.

Mallinckrodt argues Ms. Trexler properly applied the *Georgia-Pacific* factors and tied them to her proposed royalty. (D.I. 395 at 32). Airgas agrees that Ms. Trexler analyzed the factors, but it argues she did not explain how she calculated the lump sum royalty using the factors. (D.I. 403 at 17).

Mallinckrodt points to four factors analyzed by Ms. Trexler: the parties' commercial relationship (factor five), the technical advantages of the patented technology over old technology (factor nine), the nature, commercial embodiment, and benefit to those using the patented invention (factor ten), and the portion of profits that should be credited to the patented invention as distinguished from non-patented elements (factor thirteen). (D.I. 395 at 32–33). I do not think Ms. Trexler's analysis effectively apportions the patented and unpatented elements of Airgas' product. There is nothing relevant to a "thorough and reliable [apportionment] analysis."

With respect to factor five, Ms. Trexler "analyze[d] the qualitative and quantitative data in the record to quantify Mallinckrodt's anticipated loss due to price erosion and account loss, should it license to Airgas and allow it to compete in the iNO Therapy market." (D.I. 396-2 at 71 of 378). Mallinckrodt's anticipated loss should it be forced to compete with Airgas has nothing to do with which portions of Airgas' product are covered by the unconventional features of the patents.

With respect to factors nine and ten, Ms. Trexler opines, "[Ulspira] needed to at least meet feature parity with INOmax to achieve market acceptance and certain of the features are made available through the Asserted Patents." (*Id.* at 116 of 378). Ms. Trexler gives some

explanation of the benefits of the unconventional features of the patents (*id.* at 105–11 of 378), but her overall conclusion is that Ulspira needs to achieve feature parity with INOmax. She gives no discussion or analysis of the relative importance of the sensor calibration feature or of the pre-use gas verification feature. Airgas' purported desire to match Mallinckrodt's product is not an analysis of the relative importance of the unconventional features in Airgas' product.

Factor thirteen is where Ms. Trexler explains that "consideration of the entirety of Airgas' discounted incremental at-risk profits and Mallinckrodt's discounted at-risk profits in the determination of the reasonable royalty does not require further apportionment" because "any of the Asserted Orange Book Patents is tied to the profits on the entirety of the Covered and Accused Products," and, "Airgas' FDA approval process for [Ulspira] inextricably linked the 510(k) approval of the device to the ANDA approval of the nitric oxide gas, as the approvals were contingent upon one another." (D.I. 396-2 at 129–30 of 378). Declining to apportion because Ms. Trexler thinks it is not legally necessary due to the mechanics of ANDA litigation is not apportioning. And, for reasons I explain in greater detail below, I think it is still necessarily to apportion in an ANDA case such as this one.

For the foregoing reasons, I do not think Ms. Trexler's *Georgia-Pacific* analysis effectively apportions the patented and unpatented portions of Airgas' accused device.

ii. Incremental Value

Mallinckrodt argues Ms. Trexler does consider the incremental value added by the patented invention to the infringing product under her analysis of *Georgia-Pacific* factor eleven. (D.I. 395 at 34). Mallinckrodt quotes a portion of Ms. Trexler's expert report,

> Airgas' incremental at-risk profit is the difference between the discounted profits that would have been earned if a license were obtained and ULSPIRA was launched at the anticipated launch date (i.e., begin sales in the first quarter of 2024), and the

> discounted profits that would result from a delayed FDA approval date (the "Delay Period").

(D.I. 396-2 at 119–20 of 378).

This is not incremental value added by the patented features of the invention. This is the difference between profits if Airgas had received a license and launched "on time" and profits if Airgas refused a license and was delayed in its launch due to a finding of infringement and resetting of its ANDA approval date. This has little bearing on the value of the features of Airgas' products covered by the patents.

iii. *AstraZeneca II*

Finally, Mallinckrodt argues the asserted patents cover the infringing product as a whole, analogizing to *AstraZeneca II*. (D.I. 395 at 35). This relates to Airgas' argument on entire market value.

At issue in *AstraZeneca II* were patent claims with "three key elements—the drug core, the enteric coating, and the subcoating." *AstraZeneca II*, 782 F.3d at 1338. "The combination of those elements constitutes the complete . . . product that is the subject of the claims." *Id.* Thus, that "case [did] not fit the pattern in which the entire market value rule applies" because the "patents cover the infringing product as a whole, not a single component of a multi-component product." *Id.* This was true even though "the active ingredient patents had expired at the time of the infringement and the active ingredient had thus become a 'conventional element.'" *Id.* 1337.

The court explained, "When a patent covers the infringing product as a whole, and the claims recite both conventional elements and unconventional elements, the court must determine how to account for the relative value of the patentee's invention in comparison to the value of the conventional elements recited in the claim, standing alone." *Id.* The court explained that several *Georgia-Pacific* factors, like factors nine and ten, bear directly on this issue. *Id.* Further,

> It is not the case that the value of all conventional elements must be subtracted from the value of the patented invention as a whole when assessing damages. For a patent that combines "old elements," removing the value of all of those elements would mean that nothing would remain. In such cases, the question is how much new value is created by the novel combination, beyond the value conferred by the conventional elements alone.

Id. at 1339.

Mallinckrodt argues that the asserted Orange Book patents cover Airgas' purported infringing product as a whole.

Airgas argues *AstraZeneca II* is distinguishable because it involved a drug product, not a "multi-component machine" like the one at issue here. (D.I. 403 at 18). *AstraZeneca II*'s holding was not that the market value rule is never applicable to pharmaceutical contexts, or that the market value rule always applies to non-pharmaceutical contexts. The holding was that the entire market value rule was inapplicable to that case, at least because the "patents cover the infringing product as a whole, not a single component of a multi-component product." *AstraZeneca II*, 782 F.3d at 1338.

Airgas argues the patents do not cover its purportedly infringing product "as a whole," but rather certain patents cover certain features of the product. (D.I. 403 at 19). I do not have accept Airgas's argument as it is framed. Each patent stands on its own. They have different inventions. Even assuming that every conventional and unconventional feature of the accused products is covered by some limitation of at least one of the asserted patents, that does not mean that apportionment patent-by-patent is not required. I think the law requires that. Further, as a practical consideration, the jury needs that explanation in the event that it finds infringement of some patents and non-infringement of others.

This brings us to Mallinckrodt's argument about the Orange Book, and Ms. Trexler's trio of reasonable royalties depending on which patents are found to be infringed. When an ANDA

product is found to infringe an Orange Book-listed patent, the FDA will typically, upon direction from a District Court, reset the ANDA approval date to after the expiration of the infringed patent. The asserted Orange Book patents here have three different expiration dates. Ms. Trexler created three reasonable royalties depending on the expiration. But critically, she did not adjust her royalty depending on how many of the patents are theoretically infringed. The FDA will reset the ANDA approval date for the entire product to a date after the latest-expiring infringed patent expires, regardless of how many patents are found to be infringed. Ms. Trexler adjusted the rate based only on the date. To her, the number of patents infringed does not matter. This, I think, was legal error.

While approval-resetting is a unique procedure of the FDA and ANDA litigation, Mallinckrodt cites no cases to support its damages approach. Time and again the Federal Circuit has explained that damages must be apportioned to those infringing components of the accused product, unless the patentee shows it is entitled to the full market value of the accused product. *See, e.g.*, *Ericsson*, 773 F.3d at 1226. I do not see why an ANDA would be any different. Mallinckrodt cites no cases showing that an ANDA is different in this way.

AstraZeneca II is different from this case. There, the issue was apportioning between conventional and non-conventional components claimed in an infringed patent, not patented and unpatented elements of an accused product. *AstraZeneca II*, 782 F.3d at 1337. And, though the active ingredient claimed in those patents was deemed to be "conventional" because the patents covering the active ingredient had expired, the claims were directed to a subcoating that solved a stabilization issue that had previously made it difficult to ingest the drug. *Id.* at 1328–29. Though the Federal Circuit did not explicitly say so, it reasonably follows that the patent claims including the "conventional" active ingredient were still directed to the defendant's product "as a

whole" since the subcoating was necessary for stability and delivery of the active ingredient. Here, we have multiple patents covering different features of a multi-feature product. The *AstraZeneca II* court was not presented with the issue of multiple patents covering separate elements of an accused device.

Mallinckrodt has cited no case to support its theory that infringement of one of many patents listed in the Orange Book for a drug means it does not have to apportion. I think cases on Fair, Reasonable, and Non-Discriminatory ("FRAND") licensing tend to refute Mallinckrodt's argument. *See Ericsson, Inc. v. D-Link Sys.*, 773 F.3d 1201, 1235 (Fed. Cir. 2014). In FRAND cases, "[D]istrict courts must make clear to the jury that any royalty award must be based on the incremental value of the invention, not the value of the standard as a whole or any increased value the patented feature gains from its inclusion in the standard." Just like how the value of a patent included in a standard subject to FRAND licensing is not the value of the standard as a whole, the value of a patent that covers part of an ANDA product is not the value of the ANDA product as a whole. A reasonable royalty must be based on the incremental value of the invention.

For the foregoing reasons, I think Ms. Trexler failed to properly apportion, as required in her Scenario 1 opinion. Her testimony is thus unreliable under Federal Rule of Civil Procedure 702 and is excluded.

b. Upper Bound

Second, Airgas argues Ms. Trexler improperly "calculates Mallinckrodt's future lost profits from speculative lost sales and price erosion through the Orange Book patent expiration dates." (D.I. 378 at 39). This is the "upper bound" in Ms. Trexler's reasonable royalty numbers. Mallinckrodt argues Ms. Trexler does not analyze lost profits, and Mallinckrodt does not seek

lost profits. (D.I. 395 at 38). Airgas argues Ms. Trexler "attempt[s] to shoehorn a lost profits analysis into a reasonable royalty analysis." (D.I. 378 at 39).

The issue is thus whether the upper range of Ms. Trexler's reasonable royalty is, in fact, a reasonable royalty or if it is lost profits in sheep's clothing. The only thing Mallinckrodt cites for support that the upper limit is a reasonable royalty is Airgas' expert's rebuttal report saying Ms. Trexler "is not directly alleging to have claimed lost profits." (D.I. 395 at 38) (citing D.I. 396-2 at 357 of 378). In the next sentence, however, Airgas' expert opines that Ms. Trexler "has essentially calculated alleged lost profits damages (albeit speculatively and including purported speculative price erosion damages) and attempted to present such alleged lost profits damages as reasonable royalty damages." (D.I. 396-2 at 357 of 378). While Mallinckrodt is correct that an expert can use lost profits to inform their reasonable royalty analysis, that does not mean that an expert can pass off lost profits as a reasonable royalty without the required lost profits analysis.

Mallinckrodt cites nothing in Ms. Trexler's report to show that the upper limit is a reasonable royalty, not lost profits. Ms. Trexler explains, "Based on the calculations of Mallinckrodt's expected lost profits due to Airgas from lost contracts and price erosion, I calculate Mallinckrodt's total expected losses due to Airgas from 2022 to 2034." (D.I. 396-2 at 81 of 378). Ms. Trexler determines the "net present value of Mallinckrodt's total expected lost profits due to Airgas from lost contracts and price erosion" in Scenario 1C as "$129,174,357." (D.I. 378-19 at 11–12 of 54). Ms. Trexler determines the upper limit of the reasonable royalty range for Scenario 1C as "$129,174,357." (*Id.* at 20–21 of 54). The sheep's clothing is inadequate to disguise the wolf. Her reasonable royalty range has an upper bound of lost profits. Her testimony is unreliable under Federal Rule of Civil Procedure 702 and is excluded.

Mallinckrodt states that expected profits can be taken into account in the hypothetical negotiation. That is true. It is a factor that can be considered in the *Georgia-Pacific* analysis. *See Asetek Danmark A/S v. CMI USA Inc.*, 852 F.3d 1352, 1362 (Fed. Cir. 2017). But Ms. Trexler's use of it takes a completely speculative projection of future lost profits and makes it the be-all and end-all of the analysis. The Federal Circuit has not been kind to future lost profits analysis. The Court has regularly reversed verdicts granting future lost profits. *See Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1580–81 (Fed. Cir. 1992); *Shockley v. Arcan, Inc.*, 248 F.3d 1349, 1363 (Fed. Cir. 2001); *Oiness v. Walgreen Co.*, 88 F.3d 1025, 1031–33 (Fed. Cir. 1996). The only case I am aware of that sustained an award based on "projected lost sales" is *Lam v. Johns-Manville Corp.*, 718 F.2d 1056 (Fed. Cir. 1983). The award in that case was not for "future lost profits," because the trial took place after the time period in which the projected lost sales took place. *Id.* at 1064–65. *Lam* involved a very unusual set of facts, including a two-supplier market and a long history of sales both before and after the infringement, so that it was possible to have confidence in the assumptions about what would have occurred in the absence of the infringement. There is no such confidence here. The market is not a two-supplier market; the projections go out to 2034; and Airgas was just beginning to sell anything about the time the damages reports were written. As the *Lam* Court stated, "Sales projections are seldom accurate." *Id.* at 1063. Ms. Trexler relied on Mallinckrodt's forecasted at-risk profits and offers none of her expertise to bolster the accuracy of the projections. (*See* D.I. 396-2 at 79–81 of 378).

The cumulative effect of taking long-range sales forecasts as being accurate combined with the inflation of damages that comes from not conducting a proper apportionment has resulted in an unreliable reasonable royalty analysis for Scenario 1.

Airgas' *Daubert* motion as to Ms. Trexler (D.I. 377) is granted.

4. Donald Beduhn

Mallinckrodt moves to exclude Mr. Beduhn's non-infringing alternatives testimony. Mr. Beduhn opines that a Praxair product, NOxBOXi, is a non-infringing alternative to Ulspira TS, and that combining portions of NOxBOXi with Airgas' Ulspira TS product would also be non-infringing. Mallinckrodt has three issues with Mr. Beduhn's testimony.

First, Mallinckrodt argues Mr. Beduhn's testimony is unreliable because he fails to tie his non-infringing alternative analysis to the hypothetical negotiation date. (D.I. 388 at 36). Mr. Beduhn is not a damages expert. Mallinckrodt is correct that Mr. Beduhn, in assessing non-infringing alternatives, can consider only those alternatives available before the hypothetical negotiation date. *See Aqua Shield*, 774 F.3d at 770. Airgas argues that Mr. Beduhn's proffered design-around and non-infringing alternatives "would have been available at the time of the hypothetical negotiation date." (D.I. 397 at 32). Mallinckrodt does not seem to counter that. Indeed, Mr. Beduhn considers the NOxBOXi, which was available as early as 2018 and was found not to infringe three of the asserted patents in 2019. This testimony is permissible.

Second, Mallinckrodt argues Mr. Beduhn's analysis showing NOxBOXi is non-infringing improperly hinges on one fact: that Mallinckrodt did not assert some of its patents in its suit against Praxair over the NOxBOXi. (D.I. 388 at 36). Mr. Beduhn bases his opinion on the fact that NOxBOXi was found not to infringe two of Mallinckrodt's patents asserted in this case, and an analysis of the steps performed by NOxBOXi. (*See* D.I. 397-21 at 12–18 of 18). Mallinckrodt's litigation choice is but one of several things Mr. Beduhn considers in opining that NOxBOXi is non-infringing. Mallinckrodt points to Mr. Beduhn's deposition testimony, where he says that "the basis of [his] opinion that the NOxBOXi feature is a non-infringing alternative

was that Mallinckrodt could have asserted [its] patents against Praxair but chose not to." (D.I. 401 at 17 (quoting D.I. 389-1 at 353 of 357)). That being a "basis" of Mr. Beduhn's opinion does not mean it was the sole basis. That being said, I doubt that Mr. Beduhn's expertise extends to analyzing legal decisions and being able to explain them, so I would reconsider this if it raised in the pretrial conference.

Third, Mallinckrodt argues Mr. Beduhn failed to analyze the availability of a non-infringing alternatives. (D.I. 388 at 37). Mallinckrodt argues Mr. Beduhn acknowledged that there could be regulatory delay in developing a hybrid of Ulspira TS and NOxBOXi, but that he failed to "account for this delay in his assessment of non-infringing alternatives available to Airgas." (*Id.*). Airgas argues that is a factual issue, not a technical issue. (D.I. 397 at 33). I think Airgas is right. It is Mr. Beduhn's opinion that there was a non-infringing alternative available; the holes in his opinions can be explored on cross-examination and with Mallinckrodt's own experts.

Mallinckrodt's motion (D.I. 386) is denied.

5. Kurt Karst

Airgas moves to exclude certain testimony of Mr. Karst that Ms. Trexler relies upon in her damages opinion.

Airgas argues that Mr. Karst gives improper legal opinions on FDA law and reasonable royalty law.

Airgas cites two paragraphs from Mr. Karst's report:

> There would have been a sufficient basis for concern in November 2022, when Airgas notified Plaintiffs of the company's ANDA 203144 acceptance by FDA and Paragraph IV certifications, of a district court determination of patent infringement leading FDA to convert a final ANDA 203144 approval to a tentative ANDA approval. Indeed, the governing statute and FDA's ANDA approval regulations

> specifically provide for such a conversion in light of a district court determination of infringement[.]
> . . .
> Mr. Lassman applies the incorrect legal framework in analyzing a reasonable royalty; fails to explain why Airgas would not negotiate with Plaintiffs in November 2022, ahead of a final ANDA approval in anticipation of launch; and fails to address that Airgas would be concerned about an ANDA approval conversion from final to tentative[.]

(D.I. 378-19 at 50, 53–54 of 54).

Aigas argues that, should I exclude Ms. Trexler's Scenario 1 testimony, Mr. Karst's testimony should be excluded as irrelevant under Rule 401. (D.I. 378 at 38). Mallinckrodt's only response is that the testimony is relevant because "it offers support to Ms. Trexler's reasonably royalty damages opinion." (D.I. 395 at 40). The only purpose of Mr. Karst's opinion in the above two paragraphs seems to be to support Ms. Trexler's Scenario 1 opinion. Since Ms. Trexler's Scenario 1 opinion is excluded, I think Mr. Karst's opinion in the two paragraphs is irrelevant.

Airgas' *Daubert* motion as to Mr. Karst (D.I. 377) is granted on the basis that the testimony is irrelevant and therefore would not be helpful to the jury.

6. Scott Lassman

Mallinckrodt moves to exclude certain testimony from Airgas' FDA regulatory expert, Mr. Scott Lassman. (D.I. 388 at 26). Specifically, Mallinckrodt seeks to exclude paragraphs 51 and 52 from Mr. Lassman's expert report. (*Id.*).

In both paragraphs, Mr. Lassman rebuts Mallinckrodt's expert, Mr. Kurt Karst. (D.I. 389-2 at 62–63 of 360). Mr. Karst opines on the likelihood of Airgas' ANDA being rescinded by the FDA, based on the likelihood of Mallinckrodt initiating and succeeding in patent litigation against Airgas in November 2022. (*See* D.I. 397-16 at 7 of 9).

Since I have determined the relevant hypothetical negotiation date, I think Mr. Lassman's testimony about November 2022 is likely irrelevant. I think Mr. Karst's 2022 opinions are also likely irrelevant.

Thus, I am going to grant the Daubert motion (D.I. 384) on the basis that the testimony is irrelevant and therefore would not be helpful to the jury.

C. Motion to Strike Non-Infringement Theories

Mallinckrodt moves to strike two non-infringement theories that it alleges Airgas raised for the first time in Airgas' summary judgment briefing. (D.I. 394 at 1). I have already explained why I am denying summary judgment on the bases of these two theories. *See infra* Section III.A.5. I now decide that Airgas is not barred from raising these same arguments at trial.

First, Mallinckrodt moves to strike Airgas' theory that Ulspira TS does not "verify" gas data in a way that infringes the '795 patent and the '6794 patent claims. (D.I. 394 at 4). The relevant claim limitation requires an accused device to "verify . . . gas data." (*See* '795 patent at 16:42–57). Mallinckrodt argues that Airgas previously focused its non-infringement allegations on "gas data," but now switches to focus on "verify." (D.I. 394 at 4).

I think Airgas previously disclosed this non-infringement theory. Airgas said in its final non-infringement contentions,

> Airgas does not and cannot infringe because at most Plaintiffs have identified that during a pre-use check the Ulspira confirms an expected dosage delivery of nitric oxide is within an acceptable range of actually delivered nitric oxide as measured by the gas analyzer (discussed in more detail above with respect to limitation [1.4]). This function is in no way related to verifying "gas concentration" of "gas data of the ***actual gas inside the gas source***." It cannot be, as Plaintiffs themselves previously confirmed verification happens before any gas enters the delivery system in its claims . . . .
> . . .

> The same is true of any theory Plaintiffs may have concerning a cylinder of an incorrect bottle concentration. The purpose of the pre-use check relating to expected dosage is to verify the functionality of the dosing valve system and not to confirm the bottle concentration, which is assumed.

(D.I. 394-2 at 46–47) (emphasis in original).

Airgas adequately disclosed its "verify" non-infringement theory at least in the second paragraph. Airgas explicitly alleges that the pre-use check verifies functionality and not bottle concentration (D.I. 394-2 at 47), which is exactly what Airgas alleges in its motion for summary judgment (*see* D.I. 378 at 22) ("Neither failing nor passing the performance test of the Ulspira TS verifies the concentration of gas in the attached nitric oxide cylinder."). This is reiterated in Airgas' expert's rebuttal report on non-infringement. (*See* D.I. 394-4 ¶ 529).

Second, Mallinckrodt moves to strike Airgas' theory that Ulspira TS does not deliver nitric oxide "to a patient" in a way that infringes the '046 patent claims. (D.I. 394 at 5). The relevant claim limitation requires "[a]n apparatus to deliver therapeutic gas to a patient" which includes a "calculated delivery concentration." ('046 patent at 12:6–32). Mallinckrodt argues Airgas previously focused its non-infringement contentions on the "calculated delivery concentration language," but now switches to focus on "to a patient." (D.I. 394 at 5).

Airgas points to two instances where this non-infringement contention was supposedly alleged in its expert's report. (D.I. 404 at 10). Airgas' expert opines,

> I reviewed the '046 patent and its respective asserted claims. The '046 patent is directed to a display method to show a user of a nitric oxide delivery machine whether a calculated delivery concentration of nitric oxide is in one of a target delivery region, an under-delivery of nitric oxide region, and an over-delivery of nitric oxide region. *See* '046 patent, 7:9-28. The calculated delivery concentration is based on the measured nitric oxide flow rate and the measured flow rate through the breathing circuit. *Id.*
>
> . . .
>
> The Ulspira TS does not and cannot infringe because Mr. Goodin [(Mallinckrodt's expert)] fails to identify functionality in the Ulspira TS that calculates and displays a delivery concentration of the therapeutic gas. Mr. Goodin relies on functionality

> carried out by the Gas Analyzer Module (as the alleged "control circuit") during the Pre-Use Check. . . . I disagree with Mr. Goodin's opinions.

(D.I. 394-4 ¶¶ 362, 402). Neither of these paragraphs explicitly opine that Ulspira TS does not display a calculated delivery concentration during delivery "to a patient."[6] I will thus address the *Pennypack* factors.

As to the first factor, I do not think there is any prejudice to or surprise for Mallinckrodt. One of Mallinckrodt's experts at least implies that the "calculated delivery concentration" is that of gas being delivered to a patient. (*See* D.I. 404-8 at 10 of 14) ("I understand that [the '046 patent] process improves dosing accuracy and performance of the device as it allows the user to easily determine—without significant troubleshooting efforts in the fast-paced NICU—if the device is in fact delivering the right amount of NO gas."). Other of Mallinckrodt's experts acknowledge that the pre-use test occurs before treating a patient. (*See* D.I. 404-7 at 6 of 10) ("[Airgas' Ulspira TS] contains components that communicate and verify that the right NO gas and concentration is hooked up to the machine before delivery is started to the patient."). It should be no surprise to Mallinckrodt that Airgas would allege its pre-use check does not infringe under Mallinckrodt's theory, because the pre-use check does not deliver gas to a patient.

The second factor, Mallinckrodt's ability to cure prejudice, is irrelevant since I think Mallinckrodt has suffered no harm or prejudice.

As to the third factor, Mallinckrodt argues it cannot cure the prejudice without disrupting the trial schedule. (D.I. 394 at 8). Again, I do not think there is prejudice to Mallinckrodt here. Mallinckrodt argues that, should it move for and I grant re-opening fact and expert discovery, the

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[6] The Pre-Use [Verification] Check, by definition, is before use. It would seem pretty obvious that before use does not involve delivery to a patient. Thus, saying the Pre-Use Check is not infringing because it does not deliver, or is not operable to deliver, anything to a patient is not much of a stretch from what was disclosed in the expert report.

trial date would be put at risk. (*Id.*). Even if true, Mallinckrodt fails to point out what it would seek should discovery be re-opened.

As to the fourth factor of bad faith, "Mallinckrodt does not pretend to know Airgas' motives," and instead argues that the non-infringement contention should be stricken because the other factors strongly support Mallinckrodt. (D.I. 394 at 9). For the reasons above, I disagree. There is no evidence of bad faith, so this factor weighs against striking Airgas' non-infringement theory.

As to the fifth factor, Mallinckrodt argues that Airgas has other non-infringement theories it can rely on. (D.I. 394 at 9). Airgas argues this non-infringement contention is important because it is case-dispositive. (D.I. 404 at 19). Though I deny summary judgment as to this non-infringement theory, *see supra* section III.A.5.b., and Airgas has other defenses to present at trial, I do not think this factor so outweighs the others to warrant striking the non-infringement contention.

For the foregoing reasons, Mallinckrodt's motion to strike Airgas' new non-infringement theories (D.I. 394) is denied.

IV. CONCLUSION

An appropriate order will issue.